UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/977,406	10/15/2001	Seema Garde	CLW 2 0147	4176

7590 05/18/2005

Timothy E. Nauman, Esq.
FAY, SHARPE, FAGAN,
MINNICH & McKEE, LLP
1100 Superior Avenue, 7th Floor
Cleveland, OH 44114-2516

EXAMINER	
HOLLERAN, ANNE L	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 05/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/977,406	GARDE ET AL.	
	Examiner	Art Unit	
	Anne Holleran	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *184-223* is/are pending in the application.

4a) Of the above claim(s) *197,206,211,213,218,221 and 223* is/are withdrawn from consideration.

5)☒ Claim(s) *219* is/are allowed.

6)☒ Claim(s) *184,185,187,190-196,198-205,207-210,212,214-217,220 and 222* is/are rejected.

7)☒ Claim(s) *186,188 and 189* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/19/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed 2/22/2005 is acknowledged. Claims 1-183 were canceled. Claims 184-223 were added and are pending.

Claims 197, 206, 211, 213, 218, 221 and 223, drawn to non-elected inventions, are withdrawn from consideration.

Claims 184-196, 198-205, 207-210, 212, 214-217, 219, 220 and 222 are examined on the merits.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections Withdrawn:

3. The rejections of claims 2, 3, 65-68, 73-76, 83-89, 157-168, and 175-183 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendment canceling the claims.

4. The rejections of claims 2, 3, 83-89, and 175-183 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polypeptides comprising SEQ ID NO: 5, does not reasonably provide enablement for polypeptides that consist of variants of SEQ ID NO: 5 or that comprise a sequence that is a variant of SEQ ID NO: 5. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to

make the invention commensurate in scope with these claims is withdrawn in view of the cancellation of the claims. However, this rejection is applied to new claims. See below.

5. The rejection of claims 75, 88, 161-163, and 176-178 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, because the disclosure does not adequately describe the genus of "taxol derivatives", is withdrawn in view of the cancellation of the claims.

6. The rejection of claims 2, 3, 83-89, and 175-183 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of the cancellation of the claims.

7. The rejection of claims 1-3, 65-68, 73-76, 83-89, 157-168, and 175-183 under 35 U.S.C. 102(b) as being anticipated by Sheth (U.S. Patent 5,48,011; issued June 27, 1995; cited in the IDS) is withdrawn in view of the cancellation of the claims. None of the new claims read on Sheth.

8. The rejection of claims 2, 3, 84, and 86 under 35 U.S.C. 102(e) as being anticipated by Tsai (U.S. Patent 5,994,298; issued Nov. 30, 1999; effective filing date Sep. 8, 1998) as evidenced by Tracey (U.S. Patent 6,319,894; issued Nov. 20, 2001) is withdrawn in view of the cancellation of the claims. None of the new claims read on Tsai.

9. The rejection of claims 2 and 3 under 35 U.S.C. 102(b) as being anticipated by Nolet (Nolet, S. et al., Biochimica et Biohysica Acta, 1089: 247-249, 1991) is withdrawn in view of the cancellation of the claims. None of the new claims reads on Nolet.

10. The rejection of claims 2 and 3 under 35 U.S.C. 102(b) as being anticipated by Xuan (Xuan, J.W. et al., DNA & Cell Biology, 16: 627-638, 1997) is withdrawn in view of the cancellation of the claims. None of the new clams reads on Xuan.

New Grounds of Rejection:

11. Claims 184, 185, 187, 192, 194-196 and 222 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The basis for this rejection is that claims 184, 185, 187, 192, and 194-196 introduce new matter into the specification as originally filed.

Claim 184 is drawn to a polypeptide of from 5 to 64 amino acids, wherein at least 5 contiguous amino acids of the polypeptide are identical to five contiguous amino acids of SEQ ID NO: 5. Claim 185 is drawn to a polypeptide of claim 185 that comprises the amino acids sequence of SEQ ID NO: 5. Applicants indicate that support for this claim is found in the disclosure of SEQ ID NOS: 10-88, in original claims 2 and 3 and in various passages of the specification. However, this does not appear to be the case. Original claims 2 and 3 support a claim to polypeptides comprises at least 5 contiguous amino acids of SEQ ID NO: 5, but there is

no support for a polypeptide having the size range of 5 to 64 amino acids, where the amino acids other than 5 contiguous amino acids of the polypeptide that are identical to 5 contiguous amino acids of SEQ ID NO: 5 may be any amino acid. Applicants appear to be arguing that since the maximum number of amino acids in the group consisting of SEQ ID NO: 10 to SEQ ID NO: 88 is 64, that support for this size range is provided. However, the concept "of from 5 to 64 amino acids, wherein at least 5 contiguous amino acids of the polypeptide are identical to 5 contiguous amino acids of SEQ ID NO: 5" has a different scope than what is originally contemplated. The sequences of SEQ ID NO: 10 to SEQ ID NO: 88 are all sequences that are derived from SEQ ID NO: 1 (PSP94) and all comprise SEQ ID NO: 5. Therefore, for SEQ ID NO: 10 through SEQ ID NO: 88, the amino acids outside of sequence of SEQ ID NO: 5, are determined by the sequence of SEQ ID NO: 1. What appears to have been originally contemplated by the disclosure of SEQ ID NO: 10 through SEQ ID NO: 88 was ever increasing fragments of SEQ ID NO: 1, up to a maximum size of 64 amino acids. Such a concept has a smaller scope than the concept of a polypeptide of from 5 to 64 amino acids, wherein at least 5 contiguous amino acids of the polypeptide are identical to 5 contiguous amino acids of SEQ ID NO: 5, or wherein the polypeptide comprises SEQ ID NO: 5.

Claim 187 is drawn to a polypeptide of claim 184, wherein the polypeptide comprises amino acids 1-6 of SEQ ID NO: 5. Applicants' point to the teaching of peptide 22-36, which is a peptide comprising at its last 6 places the first 6 amino acids of SEQ ID NO: 5. However, disclosure of this species is not a disclosure of a representative number of species within the genus of polypeptides defined by the language of claim 187. This is because the specification fails to teach that there is a correlation between structure of polypeptides comprising amino acids

1-6 of SEQ ID NO: 5 and the function of inhibiting the growth of a tumor cell or of inhibiting the growth of a prostatic adenocarcinoma. While peptide 22-36 may have this function, it is not clear that it has this is conferred upon it because of the presence of amino acids 1-6 of SEQ ID NO: 5. Therefore, the increase in scope from the teaching of one peptide, peptide 22-36, to a genus of peptides that comprise amino acids 1-6 of SEQ ID NO: 5 anywhere within a polypeptide that may be as large as 64 amino acids is not supported by the specification as originally filed.

Claim 192 is drawn to a polypeptide that has at least 80% of it amino acid sequence identical to the amino acid sequenced defined in SEQ ID NO: 5. This claim is construed to be drawn to peptides that comprise SEQ ID NO: 5, but have a maximum size of 18 amino acids (SEQ ID NO: 5 is 15 amino acids in length. If at least 80% of a polypeptide is identical to the sequence of SEQ ID NO: 5, then the maximum length must be 18 amino acids). There is no support for this concept in original claims 2 and 3 and the passage pointed to on page 34 of the specification, which is directed to polypeptides having 70% or 80% identity to a polypeptide of the invention. Polypeptides having 80% identity to a polypeptide of the invention describes polypeptides that may comprise less than SEQ ID NO: 5, whereas, claim 192 requires that the polypeptide comprise SEQ ID NO: 5.

Claims 194-196 are drawn to pharmaceutical compounds comprising a polypeptide claim 184. Therefore, claims 194-196 are rejected for the same reasons that claim 184 are rejected.

Claim 222 is drawn to pharmaceutical compounds comprising a polypeptide of claim 185. Therefore, claim 222 is rejected for the same reasons that claim 185 are rejected.

12. Claims 198, 201, and 203-205 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The basis for this rejection is that claims 198, 201, and 203-205 introduce new matter into the specification as originally filed.

Claims 198 and 201 are drawn to a polypeptides that have at least 40% or 80% of it amino acid sequence identical to the amino acid sequenced defined in SEQ ID NO: 5. Claim 192 is construed to be drawn to peptides that comprise SEQ ID NO: 5, but have a maximum size of 38 amino acids (SEQ ID NO: 5 is 15 amino acids in length. If at least 40% of a polypeptide is identical to the sequence of SEQ ID NO: 5, then the maximum length must be 38 amino acids). Claim 201 is construed to be drawn to peptides that comprise SEQ ID NO: 5, but have a maximum size of 18 amino acids (SEQ ID NO: 5 is 15 amino acids in length. If at least 80% of a polypeptide is identical to the sequence of SEQ ID NO: 5, then the maximum length must be 18 amino acids). There is no support for this concept in original claims 2 and 3, in SEQ ID NO: 89, or in the passage pointed to on page 34 of the specification, which is directed to polypeptides having 70% or 80% identity to a polypeptide of the invention. Polypeptides having 80% identity to a polypeptide of the invention describes polypeptides that may comprise less than SEQ ID NO: 5, whereas, claim 192 requires that the polypeptide comprise SEQ ID NO: 5. SEQ ID NO: 89 appears to be a sequence that teaches the concept of variants of SEQ ID NO: 5 itself, and not to polypeptides that comprise SEQ ID NO: 5 and have a maximum size of 38 amino acids in length.

Claims 203-205 are drawn to pharmaceutical compositions comprising a polypeptide of claim 198. Therefore, claims 203-205 are rejected for the same reasons that claim 198 is rejected.

13. Claims 214-217 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The basis for this rejection is that claims 214-217 introduce new matter into the specification as originally filed.

Claims 214-217 are drawn to pharmaceutical compositions comprising a polypeptide comprising SEQ ID NO: 5 provided that the polypeptide is not defined in SEQ ID NO: 1. The specification fails to explicitly provide support for this negative limitation. Applicants have pointed to original claims 67 and 68, which provide examples of specific peptides that happen to fall within this genus. However, original claims 67 and 68 do not support the general concept of polypeptides comprising SEQ ID NO: 5, but which are not the polypeptide of SEQ ID NO: 1, because the subject matter of these claims is not representative of the entire genus.

14. Claims 184, 185, 187, 190-196, 198-205, 207-210, 212, 214-217, 220 and 222 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polypeptides that inhibit the growth of prostatic adenocarcinoma, does not reasonably provide enablement for polypeptides that inhibit the growth of any type of tumor cell. The specification

does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation would be required to practice the full scope of the claimed inventions are: 1) quantity of experimentation necessary; 2) the amount of direction or guidance presented in the specification; 3) the presence or absence of working examples; 4) the nature of the invention; 5) the state of the prior art; 6) the relative skill of those in the art; 7) the predictability or unpredictability of the art; and 8) the breadth of the claims. See In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988).

The claimed inventions are drawn to polypeptides and to pharmaceutical compositions, where the polypeptides are polypeptides that inhibit the growth of any tumor cells. The rejected claims are drawn to various genuses and subgenuses that are defined structurally and by a functional limitation of inhibiting the growth of tumor cells. However, the specification fails to provide any examples beyond the example of inhibiting the growth prostate cancer cells, and the parent compound, PSP94 does not appear to inhibit the growth of any other type of tumor cell. Furthermore, the specification fails to teach any type of mechanism for how prostate tumor cell growth is inhibited so that it is not possible to predict if other types of tumor cells might respond in the same way that prostate tumor cells respond. Therefore, the full scope of the claimed inventions is not enabled by the teachings of the specification, because further experimentation is required. This further experimentation is undue experimentation because it is not routine experimental work with a predictable outcome, but instead is directed to experimentation on the invention itself to discover a property that may not exist. In view of the lack of teachings in the specification directed to the ability of any of the exemplified polypeptides to inhibit the growth

of tumor cells other than prostate tumor cells and in view of the unpredictability of which tumor types might be responsive to which polypeptides that fall within the claimed genuses and subgenuses, the specification fails to support the full scope of the claimed inventions.

Claims 207-210 are rejected, because of the intended use of the claimed pharmaceutical compositions is interpreted to be broadly drawn to the treatment of any tumor type. However, for the reasons set forth above, claims 207-210 appear to be enabled only for pharmaceutical compositions for the treatment of prostatic adenocarcinoma.

15. Claims 184 and 187 are rejected under 35 U.S.C. 102(b) as being anticipated by Xuan-II (Xuan, J.W. et al, Journal of Cellular Biochemistry 65: 172-185, 1997).

Claim 184 is drawn to a polypeptide that comprises at least 5 amino acids of SEQ ID NO: 5, wherein the polypeptide is from 5 to 64 amino acids in length and wherein the polypeptide inhibits the growth of a tumor cell or inhibits the growth of prostatic adenocarcinoma. Claim 187, dependent from claim 184, is drawn to a polypeptide that comprises amino acids 1-6 of SEQ ID NO: 5.

Xuan-II teaches small peptides derived from PSP94. One peptide, referred to as M23 (see Figure 1) comprises amino acids 1-12 of SEQ ID NO: 5 (M23 is defined as amino acids 21-42 of PSP94, which has the sequence of SEQ ID NO: 1) and therefore, meets the structural limitations of claims 184 and 187. Xuan-II is silent on whether M23 inhibits the growth of tumor cells or of prostatic adenocarcinoma cells. However, applicants have indicated that support for claim 187 is the teaching in the specification of peptide 22-36, which is a peptide derived from PSP94(amino acids 22-36 of PSP94, SEQ ID NO: 1) and which has the function of

inhibiting the growth of prostatic adenocarcinoma cells. Because peptide M23 of Xuan-II comprises peptide 22-36 of the instant specification, it appears that the peptide M23 must inherently have the functional properties of peptide 22-36. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1997). See MPEP 2112.02. Therefore, Xuan-II teaches a peptide that is the same as that claimed.

Conclusion

Claim 219 is allowable. Claims 186, 188, 189 are objected to for depending from a rejected claim.

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (571) 272-0833. Examiner Holleran can normally be reached Monday through Friday, 9:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at (571) 272-0787.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 571-1600.

Anne L. Holleran
Patent Examiner
May 13, 2005

ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER